

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF GEORGIA

SUSAN S. JEFFCOAT-CANTER )  
Plaintiff, )  
v. )  
MENTOR WORLDWIDE, LLC, ) 4-13-cv-301 (CDL)  
a Delaware limited liability company, )  
Defendant. ) JURY TRIAL DEMANDED

## COMPLAINT

COMES NOW Plaintiff, Susan S. Jeffcoat-Canter, by and through her attorney of record, and for her causes of action against Defendant Mentor Worldwide, LLC (“Mentor”) alleges and aver as follows:

## **GENERAL ALLEGATIONS**

### **Parties**

1. Plaintiff is now and was at all times relevant resident of the State of North Carolina.
2. Defendant Mentor is a Delaware limited liability company which has its principal place of business in California at 201 Mentor Drive, Santa Barbara, California 93111. Mentor Corporation merged with and into Mentor Worldwide, LLC on December 4, 2009. All acts and omissions of Defendant as described

herein were done by its or Mentor Corporation's agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownerships.

**Jurisdiction and Venue**

3. This Court has jurisdiction over this action by virtue of 28 U.S.C. § 1332, in that the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000.00) exclusive of interest and costs and because there is a complete diversity of citizenship between Plaintiff and Defendant. The Court also has personal jurisdiction over the parties pursuant to the Court's Direct Filing Order dated December 12, 2011. Plaintiff states that but for this allowance, Plaintiff would have filed in the United States District Court for the Middle District of North Carolina, Winston-Salem Division. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings, this case be transferred to the United States District Court for the Middle District of North Carolina, Winston-Salem Division.

4. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the fact that Defendant is doing business in this judicial district, subjecting

Defendant to personal jurisdiction in this action and making it a “resident” of this judicial district.

5. At all relevant times, Defendant expected or should have expected that its acts would have consequences within the United States of America and in the Middle District of North Carolina, Winston-Salem Division in particular.

### **FACTUAL ALLEGATIONS**

6. This is an action to recover damages for personal injuries suffered by Plaintiff, who has been treated with the prescription medical device ObTape, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendant.

7. The injuries suffered by Plaintiff were caused by the wrongful acts, omissions, and fraudulent representations of Defendant.

8. At all times material hereto, the ObTape sling was designed, developed, manufactured, tested, packaged, advertised, promoted, marketed,

distributed, labeled, and/or sold by Defendant herein, for use by individuals including Plaintiff.

9. At all times herein mentioned the officers and directors of Defendant participated in, authorized and directed the production and promotion of the ObTape sling when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of the ObTape sling and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff.

10. The ObTape sling was promoted by Defendant as a safe and effective treatment for female urinary incontinence that could be installed by urologists in their patients quickly and on an outpatient basis. Plaintiff and/or her physicians relied on Defendant's promises of safety. What Plaintiff received, however, was not a safe device, but a device known by Defendant to cause serious internal injuries.

11. Plaintiff was implanted with an ObTape sling on February 17, 2005 at Novant Health Forsyth Medical Center, in Winston Salem, North Carolina, which was designed, manufactured, packaged, labeled, distributed and sold by Defendant. The ObTape sling was intended to treat Plaintiff for stress urinary incontinence, the

use for which Defendant marketed the product. Plaintiff's treating physicians implanted the ObTape sling properly and appropriately.

12. Plaintiff underwent surgery to attempt to remove Defendants' PRODUCT during a corrective surgery on December 15, 2005 at Novant Health Forsyth Medical Center, in Winston Salem, North Carolina.

13. After, and as a result of the implantation of the ObTape sling on July 21, 2005, Plaintiff has suffered extensive and multiple infections, erosion of the mesh, pain and painful intercourse. As a result of having the ObTape sling implanted, Plaintiff has and will continue to experience mental and physical pain and suffering of multiple surgeries and sustained permanent injuries.

14. At all times material hereto, Defendant failed to comply or properly comply with Federal law in connection with the ObTape sling.

15. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the ObTape sling to physicians and patients without adequate warnings.

16. Had Defendant properly disclosed the risks associated with the ObTape sling, Plaintiff would not have used it.

17. As alleged herein, as a direct and proximate result of Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the ObTape sling, Plaintiff suffered and will continue to suffer severe and permanent physical injuries. Plaintiff continues to endure substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

**COUNT 1**  
**Negligence**

18. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

19. Defendant, at all relevant times, had a duty to exercise reasonable care in the design, manufacture, labeling, testing, distributing, advertising, marketing, promoting, warning and/or sale of the ObTape sling into the stream of commerce,

including a duty to ensure that the ObTape sling did not cause users to suffer from reasonably foreseeable, dangerous side effects and serious health problems.

20. Defendant at all relevant times knew or, in the exercise of reasonable care, should have known that the ObTape sling was of such a nature that it was not properly designed, manufactured, labeled, tested, distributed, advertised, marketed, promoted and/or sold with the proper warnings, and was unreasonably likely to injure the ObTape sling's users.

21. Defendant so negligently and carelessly designed, manufactured, labeled, tested, examined, distributed, advertised, marketed, promoted, sold and/or supplied the ObTape sling, that it was dangerous and unsafe for the use and purpose for which it was intended.

22. Defendant was aware of the probable consequences of the ObTape sling.

23. Defendant knew or should have known the ObTape sling would cause serious injury; however, it failed to disclose the known or knowable risks associated with the ObTape sling.

24. Defendant willfully and deliberately failed to avoid those consequences, and in doing so, they acted in conscious disregard of the safety of the Plaintiff.

25. Defendant owed a duty to Plaintiff to adequately warn her and her treating physicians, of the risks associated with the ObTape sling and the resulting harm and risk it would cause patients.

26. Defendant breached its duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the ObTape sling.

27. As a direct and proximate result of Defendant's breach, the ObTape sling used to treat Plaintiff's female urinary incontinence failed, resulting in the Plaintiff suffering serious injury, pain and harm.

28. As result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff

has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

29. Defendant's conduct in continuing to market, sell and distribute the ObTape sling after obtaining knowledge that they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional punitive damages in such a sum as would serve to punish Defendant and to deter others from similar conduct in the future.

WHEREFORE, Plaintiff prays for judgment in Count I against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT II**  
**Strict Product Liability – Defective Design**

30. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

31. At all times relevant herein, Defendant was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the ObTape sling.

32. The ObTape sling is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

33. At all times relevant herein, the ObTape sling was expected to reach, and in fact did reach, consumers in the State of North Carolina and throughout the United States without substantial change in the condition in which it was sold.

34. At all times relevant herein, Defendant intended for its ObTape slings to be surgically implanted into members of the general public, including Plaintiff, and knew or should have known that the ObTape slings would be surgically implanted into members of the general public, including Plaintiff.

35. The implantation of the ObTape sling into Plaintiff was reasonably foreseeable and was used in the manner for which it was intended by the Defendant.

36. At all times relevant herein, the ObTape sling was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective and unreasonably dangerous

condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

- a. When placed in the stream of commerce, the ObTape sling contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting individuals, including Plaintiff to risks that exceeded the benefits of the ObTape sling, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the ObTape sling, and/or the need for additional surgery as well as other severe and permanent health consequences;
- b. When placed in the stream of commerce, the ObTape sling was defective in design, making the use of the ObTape sling more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with alternatives;
- c. The ObTape sling's design defects existed before it left the control of Defendant;
- d. The ObTape sling was insufficiently tested;
- e. The ObTape sling caused harmful side effects that outweighed any potential utility; and

f. The ObTape sling was not accompanied by adequate instruction and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendant liable to Plaintiff.

37. In addition, at the time the ObTape sling left the control of the Defendant, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the ObTape sling. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the ObTape sling's utility.

38. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her

injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count II against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT III**  
**Strict Product Liability – Manufacturing Defect**

39. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

40. At all times relevant herein, the Defendant was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the ObTape sling.

41. At all times relevant herein, the ObTape sling was expected to reach, and did reach, consumers in the State of North Carolina and throughout the United States without substantial change in the condition in which it was sold.

42. The implantation of the ObTape sling into Plaintiff was reasonably foreseeable and was used in the manner for which it was intended by the Defendant.

43. At all times relevant herein, the ObTape sling was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendant in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

- a. When placed in the stream of commerce, the ObTape sling contained manufacturing defects which rendered the product unreasonably dangerous and subjected Plaintiff to risks that exceeded the benefits of the ObTape sling, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the ObTape sling, and/or the need for additional surgery as well as other severe and permanent health consequences;
- b. The ObTape sling's manufacturing defects occurred while the product was in the possession and control of the Defendant;
- c. The ObTape sling was not made in accordance with Defendant's specifications or performance standards; and
- d. The ObTape sling's manufacturing defects existed before it left the control of Defendant.

44. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count III against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT IV**  
**Strict Product Liability – Failure to Warn**

45. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

46. The ObTape sling was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert

consumers, including Plaintiff herein, of the dangerous risks and reactions associated with the ObTape sling including but not limited to its propensity to cause injury, subjecting Plaintiff to risks that exceed the benefits of the ObTape sling, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the ObTape sling and/or the need for additional surgery as well as other severe and permanent health consequences, notwithstanding Defendant's knowledge of an increased risk of these injuries and side effects over other forms of treatment for female urinary incontinence.

47. At all times relevant herein, Defendant was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the ObTape sling.

48. At all times relevant herein, Defendant intended for the ObTape sling to be surgically implanted into members of the general public, including Plaintiff, and knew or should have known that the product would be surgically implanted into members of the general public, including Plaintiff.

49. Placement of the ObTape sling into Plaintiff was reasonably foreseeable and was used in the manner for which it was intended by Defendant.

50. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

51. Defendant, as manufacturer, designer, distributor, and/or seller of the ObTape sling is held to the level of knowledge of an expert in the field.

52. Plaintiff, individually and through her physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendant.

53. The warnings that were given by Defendant were not accurate, clear and/or were ambiguous.

54. The warnings that were given by Defendant failed to properly warn physicians of the increased risks associated with the ObTape sling, subjecting Plaintiff to risks that exceeded the benefits of the product, including but not limited to the risks of developing serious and dangerous side effects, serious infection, the need for additional procedures to remove and replace the ObTape sling and/or the need for additional surgery as well as other severe and permanent health consequences.

55. Defendant had a duty to warn Plaintiff of the dangers associated with the ObTape sling.

56. Had Plaintiff received adequate warnings regarding the risks of the ObTape sling, she would not have used it.

57. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seek actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count IV against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT V**  
**Breach of Implied Warranties**

58. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

59. Defendant designed, manufactured, marketed, distributed, supplied and sold the ObTape sling for the treatment of female urinary incontinence.

60. Defendant sold the ObTape sling which was implanted into Plaintiff, and prior to its implantation, Defendant impliedly warranted to Plaintiff, and to her physicians and health care providers, that the product was of merchantable quality and safe and fit for the use for which it was intended.

61. Plaintiff and her physicians and health care provider reasonably relied on Defendant's judgment, statements and indications that the ObTape sling was fit for such use.

62. At the time of the sale of the ObTape sling, Defendant knew, or should have known, that the ObTape sling's intended use was to be surgically implanted into the body for the treatment of female urinary incontinence.

63. At the time of Plaintiff's receipt and/or use of the ObTape sling, the ObTape sling was being used for the purpose and in a manner normally intended, namely for the treatment of female urinary incontinence.

64. Due to Defendant's wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the ObTape sling until after it was implanted in Plaintiff.

65. When the ObTape sling was distributed into the stream of commerce and sold by Defendant, it was unsafe for its intended use, and not of merchantable quality, as warranted by Defendant in that it had very dangerous propensities when

used as intended and implanted into a patient's body where it could cause serious injury or harm or death to the end user.

66. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count V against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT VI**  
**Breach of Express Warranties**

67. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

68. Defendant expressly warranted and/or represented to physicians and healthcare providers that the ObTape sling was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

69. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of Defendant for use of the ObTape sling.

70. Plaintiff did so rely on the express warranties of Defendant herein.

71. The ObTape sling does not conform to the express representations because the ObTape sling is not safe and has numerous serious risks and side effects.

72. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the ObTape sling was not safe and fit for the use intended, and, in fact, produced serious injuries to the users.

73. As a result of the foregoing acts and/or omissions, Plaintiff was and still is caused to suffer and/or at a great risk of suffering serious and dangerous side effects including but not limited to serious infection, the need for additional

procedures to remove and replace the ObTape sling and/or the need for surgery as well as other severe and permanent health consequences.

74. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count VI against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT VII**  
**Fraudulent Misrepresentation**

75. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

76. Defendant falsely and fraudulently represented to the medical and healthcare community, and to Plaintiff and the general public, that the ObTape sling had been tested and was found to be safe and/or effective for the treatment of female urinary incontinence.

77. The representations made by Defendant were, in fact, false.

78. When said representations were made by Defendant, it knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

79. These representations were made by Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community, to recommend, prescribe, dispense and/or purchase the ObTape sling for the treatment of female urinary incontinence, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the general public.

80. At the time the aforesaid representations were made by Defendant and, at the time Plaintiff was treated with the ObTape sling, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

81. In reliance upon said representation, Plaintiff was induced to and did use the ObTape sling, thereby sustaining severe and permanent personal injuries, including but not limited to serious infection, the need for additional procedures to remove the ObTape sling, as well as other severe and permanent health consequences.

82. Defendant knew and was aware or should have been aware that the ObTape sling had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

83. Defendant knew or should have known that the ObTape sling had the potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

84. Defendant brought the ObTape sling to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

85. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of

earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count VII against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT VIII**  
**Fraudulent Concealment**

86. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

87. At all times during the course of dealing between Defendant, Plaintiff, and Plaintiff's' healthcare providers, Defendant misrepresented the safety of the ObTape sling for its intended use.

88. Defendant knew or was reckless in not knowing that its representations were, in fact, false.

89. In representations to Plaintiff and Plaintiff's healthcare providers, Defendant fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

- a. the ObTape sling was not as safe as other similar drugs and medications indicated for the treatment of female urinary incontinence;
- b. the ObTape sling was defective, and that it caused dangerous side effects, including but not limited the risk of developing serious infections and permanent scarring.
- c. the ObTape sling was manufactured negligently;
- d. the ObTape sling was manufactured defectively;
- e. the ObTape sling was manufactured improperly;
- f. the ObTape sling was designed negligently;
- g. the ObTape sling was designed defectively; and
- h. the ObTape sling was designed improperly.

90. Defendant was under a duty to disclose to Plaintiff and Plaintiff's healthcare providers the defective nature of the ObTape sling, including but not limited to the risk of developing serious infection and permanent scarring associated with the use of the ObTape sling.

91. Defendant had sole access to material facts concerning the defective nature of the ObTape sling and its propensity to cause serious and dangerous side effects, and hence cause damage to persons who used the ObTape sling, including Plaintiff in particular.

92. Defendant's concealment and omissions of material facts concerning, inter alia, the safety of the ObTape sling was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the ObTape sling, and to cause them to purchase, prescribe, dispense and/or use the product.

93. Defendant knew that Plaintiff and Plaintiff's healthcare providers had no way to determine the truth behind Defendant's concealment and omissions, as set forth herein.

94. Plaintiff, as well as Plaintiff's physicians, hospitals and healthcare providers, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

95. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred

significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count VIII against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**COUNT IX**  
**Negligent Misrepresentation**

96. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

97. Defendant had a duty to represent to the medical and healthcare community and to Plaintiff, and the general public that the ObTape sling had been tested and found to be safe and effective for the treatment of female urinary incontinence.

98. The representations made by Defendant were, in fact, false.

99. Defendant failed to exercise ordinary care in the representation of the ObTape sling, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendant negligently misrepresented the ObTape sling's high risk of unreasonable, dangerous side effects including, but not limited to, the risk of developing serious infection and permanent scarring.

100. Defendant breached its duty in misrepresenting the ObTape sling's serious side effects to the medical and healthcare community, to the Plaintiff, and the public in general.

101. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. She has endured, and will continue to endure, substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Her injuries and damages are permanent and will continue into the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff prays for judgment in Count IX against Defendant Mentor for damages in excess of Seventy-Five Thousand Dollars (\$75,000.00), which is fair and reasonable, costs herein expended, punitive damages to punish and deter any such conduct in the future and such other relief as the Court deems just and proper under the circumstances.

**DEMAND FOR JURY TRIAL**

Plaintiff Susan S. Jeffcoat-Canter hereby demands a trial by jury in this case as to such issues so triable.

This 15<sup>th</sup> day of July, 2013.

Respectfully submitted,

WARSHAUER LAW GROUP, P.C.

By: /s/ Darl H. Champion, Jr.  
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